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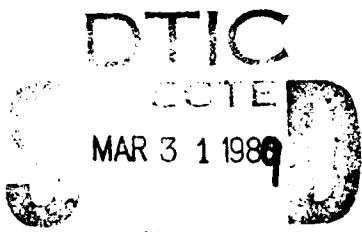
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REPORT NO T2-89

POPULATION SCREENING FOR BLOOD LIPID LEVELS AND RELATED CORONARY HEART DISEASE RISK FACTORS AMONG U.S. ARMY BASIC TRAINEES

U S ARMY RESEARCH INSTITUTE
OF
ENVIRONMENTAL MEDICINE
Natick, Massachusetts

NOVEMBER 1988



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UNITED STATES ARMY
MEDICAL RESEARCH & DEVELOPMENT COMMAND

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cholesterol levels often found in 16-20 year olds. Serum cholesterol levels between 200-239 mg/dl were found in 3 of the 125 males (3%) and 11 of the 126 females (9%). Serum cholesterol levels above 239 mg/dl were not observed. Serum cholesterol levels could not be determined for seven trainees.

A family history of high blood pressure was the most frequently identified CHD risk factor obtained from the Basic Trainees' medical histories (54% of the males and 55% of the females). The incidence of a family history of premature CHD, high cholesterol, stroke, and diabetes were identified by 14-26% of the males and 16-28% of the females depending upon the risk factor.

Trainees were prohibited from smoking during basic training; however, prior cigarette use was reported by 43% of the males and 37% of the females. Of the basic trainees who quit smoking cigarettes just prior to basic training, 40% of the males said that they would resume smoking cigarettes after completion of basic training. Only 18% of the females said that they definitely would resume smoking; 58% were undecided.

Blood lipid profiles were determined for 40 males and 39 females. Males had a mean total cholesterol (TC) level of 149 ± 29 mg/dl (mean \pm SD), mean LDL cholesterol (LDL-C) levels of 92 ± 27 mg/dl, and mean HDL cholesterol (HDL-C) levels of 51 ± 12 mg/dl. Females had mean TC levels of 165 ± 26 mg/dl, mean LDL-C levels of 98 ± 25 mg/dl, and HDL-C levels of 59 ± 14 mg/dl. The mean TC/HDL-C and LDL-C/HDL-C ratios were 3.05 and 1.93 for males and 2.87 and 1.73 for females.

Overall, there was a relatively good agreement between the blood lipid analysis methods used at Louisiana State University and the Kodak Ektachem DT 60 Analyzer. The LSU methods appeared to be somewhat more conservative than the Kodak Analyzer. Correlations between the two methods were 0.99 for TC, 0.93 for triglycerides, and 0.67 for HDL-C.

The results of this study along with findings taken from other military studies indicate that intervention programs to lower CHD risk factors should start early in a soldier's career.

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DISCLAIMER STATEMENT

The views, opinions, and findings contained in this report are those of the authors and should not be construed as an official Department of the Army position, policy, or decision, unless so designated by other official documentation.

Human subjects participated in these studies after giving their free and informed consent. Investigators adhered to AR 70-25 and USAMRDC Regulation 70-25 in Use of Volunteers in Research.

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TECHNICAL REPORT T2-89

POPULATION SCREENING FOR BLOOD LIPID LEVELS
AND RELATED CORONARY HEART DISEASE RISK
FACTORS AMONG U.S. ARMY BASIC TRAINEES

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ABSTRACT

The U.S. Army is actively promoting healthy lifestyles. A major goal of the Army Health Promotion Program is to reduce the incidence of coronary heart disease (CHD) risk factors. The purpose of this study was to determine the incidence of CHD risk factors found among U.S. Army Basic Trainees. Total serum cholesterol levels, medical histories, tobacco use, and dietary intakes were determined for 258 male and female Basic Trainees during their first to third week of Basic Training (dietary intakes are discussed in a separate technical report). Triglyceride, HDL-cholesterol, and LDL-cholesterol levels also were determined for 79 of the 258 participants. Blood lipids were determined by two different methods to test the agreement between different methods.

The mean total serum cholesterol level for males (mean age 19) was 140 ± 25 mg/dl (Mean \pm SD) and for females (mean age 20) 162 ± 28 mg/dl. Although these serum cholesterol levels appear low, they may be somewhat misleading due to an "adolescent drop" in serum cholesterol levels often found in 16-20 year olds. Serum cholesterol levels between 200-239 mg/dl were found in 3 of the 125 males (3%) and 11 of the 126 females (9%). Serum cholesterol levels above 239 mg/dl were not observed. Serum cholesterol levels could not be determined for seven trainees.

A family history of high blood pressure was the most frequently identified CHD risk factor obtained from the Basic Trainees' medical histories (54% of the males and 55% of the females). The incidence of a family history of premature CHD, high cholesterol, stroke, and diabetes were identified by 14-26% of the males and 16-28% of the females depending upon the risk factor.

Trainees were prohibited from smoking during basic training; however, prior cigarette use was reported by 43% of the males and 37% of the females. Of the basic trainees who quit smoking cigarettes just prior to basic training, 40% of the males said that they would resume smoking cigarettes after completion of basic training. Only 18% of the females said that they definitely would resume smoking; 58% were undecided.

Blood lipid profiles were determined for 40 males and 39 females. Males had a mean total cholesterol (TC) level of 149 ± 29 mg/dl (mean \pm SD), mean LDL cholesterol (LDL-C) levels of 92 ± 27 mg/dl, and mean HDL cholesterol (HDL-C) levels of 51 ± 12 mg/dl. Females had mean TC levels of 165 ± 26 mg/dl, mean LDL-C levels of 98 ± 25 mg/dl, and HDL-C levels of 59 ± 14 mg/dl. The mean TC/HDL-C and LDL-C/HDL-C ratios were 3.05 and 1.93 for males and 2.87 and 1.73 for females.

Overall, there was a relatively good agreement between the blood lipid analysis methods used at Louisiana State University and the Kodak Ektachem DT 60 Analyzer. The LSU methods appeared to be somewhat more conservative than the Kodak Analyzer. Correlations between the two methods were .99 for TC, .93 for triglycerides, and .67 for HDL-C.

The results of this study along with findings taken from other military studies indicate that intervention programs to lower CHD risk factors should start early in a soldiers career.

INTRODUCTION

Army leaders are emphasizing the benefits of a healthy lifestyle in maintaining combat readiness and lifelong good health throughout the Army Community. During the last decade, Army personnel management procedures have focused on increasing the soldier's physical and mental fitness and on decreasing the incidence of lifestyle behaviors which adversely affect the soldier's health and well being. These new or changed procedures are concentrating on preventing rather than treating the disease.

The Army Health Promotion Program, Fit to Win, was established recently in compliance with DoD Directive 1010.10 (DoD Health Promotion Policy) and AR 600-32 (Army Health Promotion Policy). This program was designed to integrate all existing and future health promotion/initiatives into one comprehensive installation effort and to establish an on-going health risk appraisal program (1,2). This multi-faceted health intervention program contains elements encompassing tobacco use, stress management, hypertension, nutrition, physical conditioning, and substance abuse. A major goal of the Fit to Win Program is to reduce the risk of coronary heart disease (CHD) within the Army Community (2).

Another Army effort to lower CHD risk has been the introduction of several nutrition initiatives into the Army Food Service Program. Overall, these initiatives have been designed to decrease the soldier's consumption of dietary fat, cholesterol, and sodium; to increase the nutritional knowledge and awareness of the soldier and food service personnel; and to provide lower calorie but nutritious menu alternatives for soldiers eating in a garrison dining facility (3).

Following a 1985 Worldwide Nutrition Conference, the Office of the Deputy Chief of Staff of Logistics (ODCSLOG) tasked the Military Nutrition Division, U.S. Army Research Institute of Environmental Medicine (USARIEM) with evaluating the nutrient intakes of soldiers subsisting in U.S. Army garrison dining facilities and to evaluate the effectiveness of the nutrition initiatives (3). The present study was the fourth of that on-going series. Additional data were collected to support an OTSG request to evaluate blood lipid levels of basic trainees (Appendix A).

Overall study objectives were to collect and analyze both nutritional data and cardiovascular risk data from U.S. Army Basic Trainees. The purpose of this technical report is to present the information obtained from the cardiovascular risk appraisal phase of the study. The nutritional assessment portion of the study will be presented in separate technical reports.

REVIEW OF LITERATURE

Coronary heart disease (CHD) is a major cause of death and disability in the United States. Within the U.S. military population, CHD is the second leading cause of death after accidents (2). The disease process is very complex and is associated with various combinations of risk factors, many of which can be controlled (4,5,6,7,8).

The association between CHD, atherosclerosis, and high blood cholesterol levels was first discussed in the landmark study conducted on U.S. soldiers killed in action during the Korean conflict (9). Although this association has been controversial, results from studies such as the Framingham Study, the Multiple Risk Factor Intervention Trial, and the Lipid Research Clinics Coronary Primary Prevention Trial clearly show a causative relationship (5,10,11).

Atherosclerotic based CHD in early childhood is now well established. Lipid deposits have been identified in the aortas of children as young as three years of age (12). Other pathological studies have reported clinically significant raised aortic lesions in individuals below the age of 20 (13,14). Ante mortem levels of CHD risk factor variables such as blood cholesterol and blood pressure have been related to post mortem atherosclerotic lesions in children and young adults (15). Although these lesions have been found in a young population, the individual rate of atherogenesis is highly variable and dependent upon a multiplicity of major coronary risk factors (8).

The determination of serum total cholesterol levels is one of the most widely used methods to initially screen for individuals who are at risk of

developing CHD. The Adult Treatment Panel of the National Cholesterol Education program (NCEP) is recommending that serum total cholesterol be measured in all adults age 20 and over at least once every five years. This panel was established by the National Heart, Lung, and Blood Institute to establish guidelines and strategies to reduce blood cholesterol levels in both individuals and in the general population. Recommendations for individuals below 20 years of age have not been established yet (4).

The NCEP has established these risk categories for different levels of serum total cholesterol for both males and females of all ages. Serum total cholesterol levels below 200 mg/dl are classified as "desirable," those 200 to 239 mg/dl as "borderline-high," and those 240 mg/dl and above as "high." These classifications are based upon findings of several epidemiological studies and indicate where statistically significant increases in CHD risk occur (4).

Although serum total cholesterol levels are an important indicator of CHD risk, determination of low-density lipoprotein cholesterol (LDL cholesterol) and high-density lipoprotein cholesterol (HDL cholesterol) levels for further diagnosis and/or risk factor analysis is necessary (4). The majority of blood cholesterol is found in combination with these lipoproteins and both play an important role in cholesterol transport in the body. LDL's are produced from very low-density lipoprotein (VLDL) remnants which are the product of VLDL degradation in the intravascular space. VLDL is a triglyceride-rich lipoprotein produced by the liver. When the body's transport system is working properly, cholesterol-enriched LDL's and VLDL-remnants are taken up and metabolized by the liver via hepatic LDL receptors. High blood cholesterol levels may be the result of either overproduction of LDL's and VLDL's and/or

the decreased capacity of the liver to clear these lipoproteins at the LDL receptor sites. The reasons for decreases in hepatic LDL receptor activity in individuals without familial hypercholesterolemia are not precisely known, but may be the result of aging, a genetic predisposition, or excess dietary saturated fat and cholesterol (8). The role of HDL's in cholesterol transport is to remove cholesterol from extrahepatic tissues for transport to the liver, either directly or via LDL's and VLDL's, where it is metabolized to bile acids for excretion (8). The Framingham study demonstrated that there is an inverse relationship between HDL levels and CHD (5).

LDL cholesterol has been called "bad" cholesterol due to it's atherogenic properties, whereas HDL cholesterol is considered "good" cholesterol for its' apparent anti-atherogenic qualities. The complex relationship between total cholesterol, HDL cholesterol and LDL cholesterol makes discussions of CHD prediction rather complex. Efforts to simplify these relationships have led to the development of summary estimates of cholesterol (16). Two summary estimates were tested on the data obtained from the Framingham Heart Study (16). The ratio of total cholesterol to HDL cholesterol and the ratio of LDL cholesterol to HDL cholesterol were tested for their appropriateness in predicting CHD development. These estimates were useful in combining cholesterol information and had strong associations with CHD development for both males and females (16).

Results from epidemiologic studies indicate that serum total cholesterol levels in populations change significantly during the human life cycle. These changes appear to be influenced by diet, sex, lifestyle and behavioral factors, and genetics (17,18). Aging appears to increase total cholesterol levels

regardless of race and sex. White females generally have higher total cholesterol levels during childhood than white males. After completion of sexual maturation, white males tend to have higher cholesterol levels until around age 50 when white females, due to menopause, again begin to demonstrate higher total cholesterol levels (18). Black children tend to have consistently higher mean total cholesterol levels than white children (17). Black male adults were shown to have somewhat lower mean total cholesterol levels than white male adults (18), although this was not a representative sample of the general population.

LDL cholesterol and HDL cholesterol levels also change with age depending upon sex and race. Levels of HDL cholesterol and LDL cholesterol are independent of each other although there is a small negative correlation in childhood and young adulthood (18). During childhood, females tend to have higher LDL cholesterol and lower HDL cholesterol levels than males. Females tend to have lower LDL cholesterol levels than males after reaching the mid-20's but higher LDL cholesterol levels after age 50 (18). Males have been found to have lower HDL cholesterol levels than females throughout adulthood (18). Black male children tend to have higher LDL cholesterol and HDL cholesterol than white male children; however, black male adults tend to have lower LDL cholesterol levels and higher HDL cholesterol levels than white male adults (18).

The NCEP recommends further lipoprotein analysis for individuals with high or borderline-high serum total cholesterol levels (4). This requires measurement of LDL cholesterol, needed for further CHD risk appraisal and ultimate treatment methods. Risk classifications based upon the LDL

cholesterol level are: LDL cholesterol levels 160 mg/dl or greater are classified as "high risk" and those 130-159 mg/dl as "borderline-high risk."

The executive director of the Adult Treatment Panel of the NCEP has estimated that one out of every four American adults may be at significant risk for CHD due to elevated cholesterol levels (19). With the advent of the Army Health Promotion Program, the U.S. Army Health Services Command (HSC) began to accumulate statistics on cholesterol levels of the Army population. Statistics compiled in the Jan-Jun 88 Cumulative Army Health Risk Appraisal Report (Table 1) indicate a gradual rise in mean cholesterol levels with increasing age in both males and females (20). These statistics were collected on a population which was approximately 87 percent active duty.

Table 1. Mean Cholesterol Levels Reported to Army Health Risk Appraisal Program (Jan-Jun 88).

| <u>Age</u> | MALE | | FEMALE | |
|-------------|----------|-------------------------------------|----------|-------------------------------------|
| | <u>N</u> | <u>Mean Cholesterol (mg/dl)</u> | <u>N</u> | <u>Mean Cholesterol (mg/dl)</u> |
| 25 or less | 18339 | 166.2 | 2986 | 178.3 |
| 26-34 | 7446 | 185.1 | 1693 | 183.2 |
| 35-39 | 2752 | 202.3 | 496 | 188.3 |
| 40 or older | 3563 | 210.6 | 1089 | 208.8 |

Statistics compiled from other military studies also depict the incidence of elevated blood cholesterol levels in the active duty population. During the 1985 CFFS-FDTE in Hawaii, approximately 40 percent of the 200 soldiers participating in the study were found to have serum total cholesterol levels greater than 200 mg/dl at the time of their pre-test screening (21). A recent

nutritional survey of U.S. Navy SEAL trainees identified 38 percent of 277 study participants as having serum total cholesterol levels above 205 mg/dl (22). Both surveys studied male samples under 30 years of age. Another U.S. Army Institute of Environmental Medicine study of Marines during an operational ration test conducted at the U.S. Marine Mountain Warfare Training Center showed similar results. Blood cholesterol levels above 200 mg/dl were found in 29% of the Marines whose cholesterol levels ranged from 103 mg/dl to 262 mg/dl (23).

These findings for military soldiers also are consistent with those of a population screening for blood cholesterol at six sites in the New York Metropolitan area (24). Thirty-four percent of the sample of males between 20-29 years of age were found to have serum total cholesterol levels greater than 200 mg/dl. The mean levels for males and females 20 to 29 years of age were almost identical (175 mg/dl and 176 mg/dl). However, only eight percent of the females had levels over 200 mg/dl (24).

Elevated blood cholesterol is the primary CHD risk factor; however, both the development and rate of the disease process can be influenced by several other factors (4,8). The NCEP uses these additional risk factors to further classify individuals whose serum total cholesterol and/or LDL cholesterol levels fall within the borderline high classifications (4). The risk factors used by the NCEP are: male gender; family history of premature CHD; cigarette smoking; hypertension; HDL cholesterol concentrations below 35 mg/dl; diabetes mellitus; history of definite cerebrovascular or occlusive peripheral vascular disease; and gross obesity (4).

The dangers associated with cigarette smoking have been widely recognized (25). Studies of U.S. military personnel, conducted prior to 1985, have reported the prevalence of cigarette smoking to be between fifty-three and forty-six percent (26,27). A 1983 survey found that cigarette smoking within the general United States population occurred in thirty-six percent of the males and twenty-nine percent of the females (28). Results of a U.S. Navy study of recruits and active shipboard service members indicated that naval personnel tended to acquire the smoking habit after shipboard experience (29). Incoming recruits were reported to have a smoking rate of twenty-eight percent and shipboard personnel fifty percent (29). Recent figures compiled for the Army Health Risk Appraisal Program during Jan-Jun 88 report current cigarette usage to be thirty-four percent for males and twenty-seven percent for females (20). A major goal of the Army Health Promotion Program is to reduce tobacco use to twenty-five percent by 1990 (2).

Other lifestyle behaviors have been reported to have positive and negative associations with CHD. Most medical personnel would not advocate alcohol use as a preventive treatment for CHD; however, moderate alcohol consumption (one to three standard drinks per day) has been correlated with a decreased incidence of CHD and with increased plasma HDL cholesterol levels (30-33). While moderate alcohol intake may appear to be beneficial heavy or greater than moderate alcohol consumption has been linked to increased cardiovascular disease, CHD, and sudden death (34,35).

Vigorous physical exercise or activity has been shown to have positive effects on blood lipid levels (36-39). Increased levels of exercise have been associated with decreased levels of triglycerides and LDL's, and increased levels of HDL's (36,38).

Use of oral contraceptives by women has been associated with a greater risk of CHD (40,41). Increases in plasma total cholesterol, VLDL cholesterol and triglycerides have been reported in oral contraceptive users (42). However, use of oral contraceptives does not appear to increase CHD risk unless a woman already has an underlying problem with atherosclerosis and has other CHD risk factors such as smoking, hypertension, and diabetes (40). In adolescent girls and young women, cigarette smoking and use of oral contraceptive pills produced additive effects on adverse serum lipoprotein changes (43).

METHODS

This study was approved by the United States Army Research Institute of Environmental Medicine and the Surgeon General of the Army's (OTSG) Human Use Review Committees (Appendix B&C). Data were collected at an U.S. Army Training and Doctrine Command (TRADOC) installation (Ft. Jackson, SC) in the southeastern United States during the first two weeks of August 1988 (Appendix D). Overall study objectives were to collect and analyze both nutritional data and cardiovascular risk data from U.S. Army Basic Trainees. The purpose of this technical report is to present the information obtained from the cardiovascular risk appraisal phase of the study. The nutritional assessment portion of the study will be presented in separate technical reports.

Specific study objectives for the cardiovascular risk phase were:

1. To determine the mean serum total cholesterol level for a representative sample of male and female soldiers undergoing U.S. Army Basic Training.
2. To determine the occurrence of related cardiovascular risk factors in a representative sample of male and female soldiers undergoing U.S. Army Basic Training.
3. To determine mean serum triglyceride, high-density lipoprotein (HDL cholesterol), and low-density lipoprotein (LDL cholesterol) levels for a subpopulation of the study sample of male and female soldiers undergoing U.S. Army Basic Training.
4. To compare the results of blood serum analysis for total cholesterol, triglycerides, and HDL cholesterol by two different methods.

Study Sample

Volunteers for the study were recruited from six companies of one training battalion which had been approved for use. The trainees were in their first to third week of basic training at the time of the study. Four of the companies were comprised of male soldiers and two of the companies were female. Each male company provided thirty-five initial volunteers and each female company seventy volunteers.

Prior to the start of data collection, the volunteers were briefed by the responsible and principal investigators for the study. Information presented in this briefing included: the purpose of the study; the data collection procedures; the subject's right to withdraw at any time from the entire study or any part of the study; the risk potential involved with the data collection procedures; the safety precautions to minimize potential risk; and the confidentiality of the data collected.

After this initial briefing, twenty-two of the initial volunteers decided not to participate in the study. No effort was made to recruit additional volunteers. Each of the remaining 258 volunteers was asked to sign a Volunteer Agreement Form (Appendix E) and to complete a Volunteer Registry Data Sheet (Appendix F).

The subjects were divided into two groups depending upon the types of data which were to be collected. Group 1 consisted of 40 males and 40 females. This group was asked to provide 10 ml blood to permit a blood lipid profile analysis. Group 2 consisted of 88 males and 90 females who provided a smaller quantity of blood for the analysis of serum total cholesterol only. Subjects from both groups were asked to provide demographic and other medical information for the assessment of additional cardiovascular risk factors.

Blood Collection Procedures

Fasting blood samples were collected from 40 males and 39 females. One female subject from Group 1 had been placed on KP duty and had already eaten before the blood samples were taken, hence no blood was taken from this individual. Blood samples required for the analysis of serum total cholesterol, triglycerides, and HDL cholesterol were drawn by venipuncture from an antecubital vein by trained phlebotomists. Approximately 10 ml of blood was drawn into serum vacutainer tubes from subjects who had not eaten for the past 11-12 hours. Compliance with this requirement for fasting was expected to be high since the basic trainee's access to food was extremely limited.

After the fasting blood samples were drawn, the blood was allowed to clot at room temperature, centrifuged and the serum aliquotted into two 2 ml tubes. Serum from one tube was used by USARIEM personnel to analyze for total cholesterol immediately after the blood was drawn. The remainder of the serum was refrigerated and shipped to the USARIEM facilities in Natick, MA where it was frozen and stored at 0°F for subsequent analysis of triglycerides and HDL cholesterol. The serum in the second tube was refrigerated and shipped to Louisiana State University Medical Center (LSU) within 48 hours for a complete lipid profile.

Approximately 0.2-0.3 ml of blood was drawn using a finger stick method from each of the subjects in Group 2. The blood was drawn into 0.3 ml serum capillary microvette tubes and centrifuged to obtain the serum. The resultant serum was immediately analyzed for total cholesterol. Serum was analyzed for 172 of the 179 subjects. Sufficient blood could not be drawn from the seven remaining subjects. These blood samples were drawn from nonfasting subjects

since serum total cholesterol does not appear to be influenced by recent food consumption (44).

Blood Shipment and Storage

The tubes containing the serum destined for LSU were placed in ice immediately after aliquotting. The tubes were kept in ice for approximately 3 hours and then refrigerated at approximately 40° F for 48 hours. The tubes were placed in containers with cold packs and shipped overnight to LSU.

The tubes containing the serum which would be analyzed at USARIEM also were placed in ice immediately after aliquotting. These tubes of serum were kept in ice for the same length of time as the LSU samples, held for 16 hours at 40° F, placed in containers with cold packs, transported to Natick, MA, and stored frozen for 18 days at 0° F. According to the methodologies furnished by Kodak, HDL cholesterol and triglyceride analyses are not affected by freezing the serum samples (45).

Serum Analysis Methods

Analyses for serum total cholesterol, triglycerides, and HDL cholesterol were performed using two different methodologies by USARIEM and LSU. At USARIEM the three blood lipids were determined on a Kodak Ektachem DT 60 Analyzer according to Kodak procedures (45). Analyses were performed by personnel who had been trained in the use of the instrument, but whose past analytical laboratory experience was limited.

The Kodak Ektachem DT 60 methodology is based on a multilayered dry slide which has been treated with test specific reagents (45). On the triglyceride slide, the serum triglycerides are dissociated from the lipoprotein complexes

by a surfactant in the slides' spreading layer. The triglyceride molecules are then hydrolyzed by lipase to yield glycerol and fatty acids (45). Subsequent reactions in the reagent layer of the triglyceride slide enzymatically phosphorylate and oxidize the glycerol molecules to hydrogen peroxide which reacts with a triarylimidazole leuco dye to form a colored compound. Colorimetric measurement by reflectance spectrophotometry of the resultant colored slide is used to quantify the serum triglyceride levels (45).

The methodologies for determining serum total cholesterol and HDL cholesterol are identical. The major difference between the two procedures is the prior separation of HDL cholesterol from the other cholesterol fractions before application to the slide. The cholesterol slides use a surfactant in the spreading layer to dissociate cholesterol and cholesterol esters from the lipoprotein complexes in the serum sample. Subsequent reactions enzymatically hydrolyze and oxidize cholesterol esters and cholesterol to hydrogen peroxide. The resultant hydrogen peroxide reacts with a triarylimidazole leuco dye to form a colored compound which is measured by reflectance spectrophotometry (45).

The Kodak Ektachem DT 60 Analyzer was calibrated for total cholesterol, triglycerides, and HDL cholesterol prior to serum analysis. Reference materials made from bovine sera and furnished by Kodak were used for the calibration procedures. Periodic quality control checks were done using a Kodak furnished standard solution (45).

For the DT 60 analyzer, 10 μ l of serum was pipetted directly onto each Kodak slide for serum total cholesterol and triglycerides analyses. Before HDL cholesterol could be analyzed, the serum had to be treated to separate the HDL

cholesterol from other lipoprotein constituents according to Kodak procedures (45). Separation was done in Kodak furnished tubes containing a 50,000 MW dextran sulfate/magnesium reagent. First, 0.5 ml of serum was mixed thoroughly in each tube for 30 seconds using a vortex mixer. After standing for approximately 5 minutes, each tube was centrifuged for 10 minutes at 1500 x g. After centrifugation, the HDL remained in the supernate fraction while the non-HDL fractions formed a pellet on the bottom of the tube. The cleared supernate (10 μ l) was then pipetted directly onto the Kodak Ektachem slide for analysis of the HDL constituents on the DT 60 Analyzer (45).

Serum total cholesterol and triglycerides were determined at LSU by enzymatic procedures on the Abbott VP Super System according to the manufacturer's protocol (46). Program numbers 87 and 20 were used respectively for total cholesterol and triglyceride measurements. Quality control materials were provided by the Center for Disease Control, Atlanta, GA. The LSU laboratory has been designated as "standardized" by the Center for Disease Control.

HDL cholesterol levels were determined after a selective precipitation of serum lipoproteins (LDL and VLDL) was made with heparin and Ca^{2+} (47-49), with some modification. This method consists of mixing serum (0.2 ml), distilled water (3.2 ml), beef-lung heparin (0.1 ml of a 2.5 g/l solution, \approx 140 USP units/mg; the Upjohn Co., Kalamazoo, MI), and CaCl_2 (0.5 mol/l, 0.5 ml) in that order. After the mixtures have stood for 15 minutes, the precipitate is centrifuged (1500 x g, 30 min), and the supernate analyzed for HDL cholesterol by the Abbott VP Super System using program number 83. Reagents supplied by Boehringer Mannheim (Diagnostic Division, Indianapolis, IN; Cholesterol, High

Performance-K, cat. no. 692905) was used for the enzymatic assay. Quality control checks were done using CDC supplied low serum cholesterol pooled samples.

The value for VLDL cholesterol plus LDL cholesterol was obtained by subtracting HDL cholesterol from total cholesterol. The estimation of LDL cholesterol and VLDL cholesterol was made by first determining the electrophoretic ratio of LDL and VLDL. Serum (10-20 μ l) was electrophoresed on agar-agarose gel plates (8.3 x 10 cm) in a barbital buffer (pH 8.6, 0.05 mol/l) at 22mA per plate (47). The lipoprotein bands, stained with Oil Red O, were scanned in a densitometer to assess the relative proportion of LDL (x) and VLDL (y), keeping $x+y=100$. The densitometric ratios were corrected on the assumption that 1.0 mg of LDL takes up the same amount of dye as 0.86 mg of VLDL (49).

The estimation of serum LDL and VLDL cholesterol concentrations was based on the corrected electrophoretic ratio of LDL and VLDL, LDL cholesterol plus VLDL cholesterol concentration (z), and the fractional cholesterol content of LDL (46.9%) and VLDL (22.2%) molecules (49). The formulas used to estimate low-density (LDL-C) and VLDL cholesterol concentrations are as follows:

$$\text{LDL-C} = (59.14xz)/(59.14x + 24.16y) \text{ mg/dl};$$

$$\text{VLDL cholesterol} = (24.16yz)/(59.14x + 24.16y) \text{ mg/dl}.$$

CHD Risk Factor Determination

A questionnaire was used to determine the occurrence of additional CHD risk factors in this basic trainee population (Appendix G). The questions presented on this instrument were similar to those used in the Army Health Risk Appraisal

Program. This methodology was chosen for the following reasons: the main purpose of this study was to determine blood lipid levels found within the sample population; time and personnel resources were limited and precluded in depth physical examinations; and the presence of risk factors such as high blood pressure, diabetes, and severe obesity were doubtful since these factors would have precluded subjects from participating in basic training.

Risk factors measured by the questionnaire included family history of CHD, diabetes, stroke, high blood pressure, and tobacco use. Other demographic information including sex, age, height, weight, race, marital status, and educational levels also were obtained via the questionnaire. The questionnaires were phrased to capture data prior to entry on basic training where appropriate.

Statistical Analysis

Automated data analysis was performed on the results using Version 3 of the SPSSx statistical package on a Digital Vax 780 computer (50). Means, standard deviations, frequencies, and percentages were calculated for the blood lipid levels found within the population over sex, race, and age. The frequency and percentage of responses to questions on the questionnaire also were determined. A paired t test was used to compare the results for serum total cholesterol, triglycerides, and HDL cholesterol by the Kodak Ektachem DT 60 analyzer and the methodologies used by the LSU laboratory.

Notification of Cholesterol Levels

Subjects were informed of their individual cholesterol levels on the last study day. Each individual was given a letter which contained his or her cholesterol level and other general information about cholesterol and coronary heart disease (Appendix H). Individuals with cholesterol levels over 200 mg/dl were advised to notify the appropriate medical officer at their next duty assignment or before if desired. When personal contact could not be made, notification was accomplished by distributing sealed letters through the appropriate training company.

RESULTS AND DISCUSSION

Demographics

Volunteer subjects participating in this study were selected from six companies of one basic training battalion. The subjects were members of the Regular Army, U.S. Army Reserve, and National Guard components with plans to work in support related Military Occupational Specialties after basic training.

The distribution of subjects by sex, race, and age is provided in Table 2. Overall the female subjects were a little older than the male subjects. The mean age for female subjects was 20 years of age compared to 19 years of age for male subjects. The greatest difference between the two groups was in the number of female subjects who were older than 25 years of age (Table 3).

The subjects came from every section of the United States with a predominance of subjects coming from the South Atlantic, East North Central, and West South Central states (Table 4). The majority of the subjects were high school graduates with more of the females having attended college (Table 5). The majority of these basic trainees were single without ever having been married (Table 6).

Table 2. Distribution of Subjects By Sex, Race, and Average Age.

| | <u>MALE</u> | | | <u>FEMALE</u> | | |
|-------------|-------------|----------|-----------------|---------------|----------|-----------------|
| <u>Race</u> | <u>N</u> | <u>%</u> | <u>Mean Age</u> | <u>N</u> | <u>%</u> | <u>Mean Age</u> |
| White | 84 | 66 | 19 | 78 | 60 | 20 |
| Black | 30 | 24 | 18 | 36 | 28 | 20 |
| Oriental | 3 | 2 | 19 | 2 | 1 | 18 |
| Hispanic | 9 | 7 | 19 | 13 | 10 | 19 |
| Other | 2 | 1 | 21 | 1 | 1 | 18 |
| Total | 128 | 100 | 19 | 130 | 100 | 20 |

Table 3. Frequency Distribution of Male and Female Subjects By Age Group.

| <u>Age Group</u> | <u>MALE</u> | | <u>FEMALE</u> | |
|------------------|-------------|----------|---------------|----------|
| | <u>N</u> | <u>%</u> | <u>N</u> | <u>%</u> |
| 19 and under | 99 | 77 | 93 | 71 |
| 20-25 | 25 | 21 | 23 | 18 |
| 26-30 | 2 | 1 | 10 | 8 |
| 31-35 | 2 | 1 | 4 | 3 |
| Total | 128 | 100 | 130 | 100 |

Table 4. Distribution of Male and Female Subjects by Region of the Country of Longest Residency.

| <u>Region</u> | <u>MALE</u> | | <u>FEMALE</u> | |
|--------------------|-------------|----------|---------------|----------|
| | <u>N</u> | <u>%</u> | <u>N</u> | <u>%</u> |
| New England | 8 | 6 | 3 | 2 |
| Middle Atlantic | 14 | 11 | 12 | 9 |
| East North Central | 23 | 18 | 28 | 22 |
| West North Central | 10 | 8 | 13 | 10 |
| South Atlantic | 27 | 21 | 14 | 11 |
| East South Central | 9 | 7 | 13 | 10 |
| West South Central | 18 | 14 | 22 | 17 |
| Mountain | 7 | 6 | 10 | 8 |
| Pacific | 10 | 8 | 14 | 11 |
| Other | 1 | <1 | 0 | 0 |
| No Response | 1 | <1 | 1 | <1 |

Table 5. Levels of Education For Male and Female Subjects.

| <u>Education Level</u> | <u>MALE</u> | | <u>FEMALE</u> | |
|------------------------|-------------|----------|---------------|----------|
| | <u>N</u> | <u>%</u> | <u>N</u> | <u>%</u> |
| Some High School | 7 | 6 | 2 | 1 |
| High School Graduate | 94 | 73 | 87 | 67 |
| Skilled Job Training | 4 | 3 | 4 | 3 |
| Some College | 17 | 13 | 32 | 25 |
| College Graduate | 6 | 5 | 5 | 4 |

Table 6. Marital Status of Male and Female Subjects.

| <u>Status</u> | <u>MALE</u> | | <u>FEMALE</u> | |
|---------------|-------------|----------|---------------|----------|
| | <u>N</u> | <u>%</u> | <u>N</u> | <u>%</u> |
| Single | 112 | 88 | 107 | 82 |
| Married | 15 | 12 | 16 | 12 |
| Separated | 0 | 0 | 2 | 2 |
| Divorced | 1 | <1 | 5 | 4 |

Serum Cholesterol Screening

Serum samples from 251 of the 258 subjects were analyzed for serum total cholesterol on the Kodak Ektachem DT 60 Analyzer. Serum samples were analyzed within one hour of the blood being drawn. The samples originated from 79 fasting and 172 non-fasting subjects. Since serum cholesterol levels do not appear to be influenced by recent food intake all results were pooled for data analysis (44).

The results of the serum total cholesterol analysis are presented in Tables 7-9. The mean cholesterol level for all males was 140 mg/dl and for all females 162 mg/dl. These mean cholesterol levels were lower than the mean cholesterol levels reported by the Army Health Risk Appraisal Program for males (166.2 mg/dl) and females (178.3 mg/dl) under 25 years old. This finding may or may not be significant due to differences in sample sizes, mean age, and sampling effects. Adolescents often experience a significant drop in cholesterol levels between ages 16-20. It also is possible that these basic trainees may have had lower mean cholesterol levels due to changes in physical activity and diet.

Although mean cholesterol levels appeared to be lower for this population than for other military populations, some trends were similar in terms of sex,

race, and age (17,18,20). Overall the mean cholesterol level for young females was higher than for young males regardless of race (Table 7). The same trend held true for age (Table 8). However, young black males taking part in this study appeared to have cholesterol levels greater than young white males (Table 7) which appeared to be opposite the results reported by Tyroler (18) in 1984.

The frequency and percentage of the male and female subjects having serum cholesterol levels within defined ranges are presented in Table 9. The ranges of 180-189 mg/dl and 190-199 mg/dl were thought to be appropriate for this young age group considering blood cholesterol values appear to increase with age and may be significant in predicting future problems (18). No individuals had a serum cholesterol levels in the high blood cholesterol classification (>240 mg/dl) as defined by the NCEP, however one female was close with a cholesterol level of 239 mg/dl. The majority of both males and females were found to have serum cholesterol levels below 179 mg/dl. A greater percentage of the female group was found to have serum total cholesterol levels within the 180-189, 190-199, and 200-239 mg/dl ranges than the male population.

Table 7. Mean Serum Total Cholesterol^a (mg/dl) Levels for Male and Female U.S. Army Basic Trainees of Various Races.

| Race | MALE | | | | FEMALE | | | | | |
|----------|------|-----------------|----|----------------|----------------|-----|-----------------|----|----------------|----------------|
| | N | Mean (mg/dl) | SD | Min (mg/dl) | Max (mg/dl) | N | Mean (mg/dl) | SD | Min (mg/dl) | Max (mg/dl) |
| White | 83 | 136 | 26 | 89 | 222 | 75 | 162 | 29 | 111 | 239 |
| Black | 28 | 151 | 24 | 114 | 202 | 35 | 165 | 26 | 112 | 210 |
| Oriental | 3 | 137 | 14 | 121 | 146 | 2 | - | - | 122 | 198 |
| Hispanic | 9 | 143 | 19 | 126 | 150 | 13 | 157 | 27 | 101 | 193 |
| Other | 2 | - | - | 126 | 150 | 1 | 126 | - | - | - |
| Total | 125 | 140 | 25 | 89 | 222 | 126 | 162 | 28 | 101 | 239 |

^aResults obtained from serum analysis by Kodak Ektachem DT 60 Analyzer.

Table 8. Mean Serum Total Cholesterola^a (mg/dl) Levels for Male and Female U.S. Army Basic Trainees of Various Age Groups.

| <u>Age</u> | <u>MALE</u> | | | | | <u>FEMALE</u> | | | | |
|------------|-------------|---------------------------------|-----------|--------------------------------|--------------------------------|---------------|---------------------------------|-----------|--------------------------------|--------------------------------|
| | <u>N</u> | <u>Mean</u> (<u>mg/dl</u>) | <u>SD</u> | <u>Min</u> (<u>mg/dl</u>) | <u>Max</u> (<u>mg/dl</u>) | <u>N</u> | <u>Mean</u> (<u>mg/dl</u>) | <u>SD</u> | <u>Min</u> (<u>mg/dl</u>) | <u>Max</u> (<u>mg/dl</u>) |
| Under 19 | 96 | 140 | 25 | 97 | 222 | 88 | 162 | 29 | 101 | 239 |
| 20-25 | 25 | 137 | 26 | 89 | 200 | 23 | 165 | 22 | 112 | 191 |
| 26-30 | 2 | 132 | 37 | 106 | 156 | 10 | 160 | 33 | 118 | 204 |
| Over 30 | 2 | 160 | 10 | 153 | 167 | 4 | 161 | 33 | 115 | 188 |
| Total | 125 | 140 | 25 | 89 | 222 | 126 | 162 | 28 | 101 | 239 |

^aResults obtained from serum analysis by Kodak Ektachem DT 60 Analyzer.

Table 9. Frequency and Percentage of Male and Female U.S. Army Basic Trainees of Various Race Having Serum Total Cholesterola^a Levels Within Defined Ranges.

| <u>Sex</u> | <u>Race</u> | <u>Under 179mg/dl</u> | | <u>180-189mg/dl</u> | | <u>190-199mg/dl</u> | | <u>200-239mg/dl</u> | |
|---------------|-------------|-----------------------|----------------------|---------------------|----------------------|---------------------|----------------------|---------------------|----------------------|
| | | <u>Freq</u> | <u>%^b</u> | <u>Freq</u> | <u>%^b</u> | <u>Freq</u> | <u>%^b</u> | <u>Freq</u> | <u>%^b</u> |
| Male | | | | | | | | | |
| | | (N=115) | | (N=4) | | (N=3) | | (N=3) | |
| White | 77 | 93 | | 2 | 2 | 2 | 2 | 2 | 2 |
| Black | 24 | 86 | | 2 | 7 | 1 | 3 | 1 | 3 |
| Oriental | 3 | 100 | | - | - | - | - | - | - |
| Hispanic | 9 | 100 | | - | - | - | - | - | - |
| Other | 2 | 100 | | - | - | - | - | - | - |
| Mean | | 92 | | 3 | | 3 | | 3 | |
| Female | | | | | | | | | |
| | | (N=88) | | (N=18) | | (N=9) | | (N=11) | |
| White | 52 | 69 | | 10 | 13 | 5 | 6 | 8 | 10 |
| Black | 23 | 66 | | 7 | 2 | 2 | 6 | 3 | 8 |
| Oriental | 1 | 50 | | - | - | 1 | 50 | - | - |
| Hispanic | 11 | 85 | | 1 | 8 | 1 | 8 | - | - |
| Other | 1 | 100 | | - | - | - | - | - | - |
| Mean | | 70 | | 14 | | 7 | | 9 | |

^aResults obtained from serum analysis by Kodak Ektachem DT 60 Analyzer.

^bPercentages were rounded and may not add up to 100%.

Additional CHD Risk Factors

A questionnaire was administered to obtain information on the occurrence of additional CHD risk factors within the sample population. In addition to CHD risk factor questions, the subjects were asked to respond to questions about alcohol use, exercise, and birth control pill use by females, since these lifestyle behaviors may affect blood lipid levels and CHD development. These results are summarized in Tables 10-16.

No male (N=128) or female (N=130) reported current treatment for high blood pressure. However, when asked if they had been informed within the last five years of having either high blood pressure or borderline high blood pressure problems, four males responded that they had been informed that they had high blood pressure, five males had been informed of borderline high blood pressure, and three females had been informed of borderline high blood pressure.

The majority of both males (90%) and females (91%) reported that they had never had their blood cholesterol levels measured. Twelve percent of the males and twelve percent of the females said that their blood cholesterol levels had been measured previously but that they could not remember the results. Only one female reported a previous blood cholesterol measurement (>240 mg/dl).

Responses to questions about family histories of premature CHD, high cholesterol levels, stroke, high blood pressure, and diabetes are summarized in Table 10. A family history of high blood pressure received the greatest number of "yes" responses (male, 54% and female, 55%). Females also appeared to have more family members with premature CHD, high cholesterol levels, and premature strokes; however, females also appeared to be better informed of family histories based upon the lower percentage of "don't know" responses. The

pattern of response was very different for knowledge about family history of diabetes. For some reason, a majority of both males (65%) and females (64%) responded "don't know" to the question.

Table 10. Percent of Male and Female U.S. Army Basic Trainees With a Family History of CHD, High Blood Cholesterol, Stroke, High Blood Pressure, and Diabetes.

| <u>Family History of</u> | <u>MALE (N=128)</u> | | | <u>FEMALE (N=130)</u> | | |
|--------------------------|---------------------|-------------|---------------------|-----------------------|-------------|---------------------|
| | <u>% Yes</u> | <u>% No</u> | <u>% Don't Know</u> | <u>% Yes</u> | <u>% No</u> | <u>% Don't Know</u> |
| CHD | 19 | 57 | 24 | 28 | 58 | 14 |
| High Cholesterol | 26 | 54 | 20 | 33 | 51 | 16 |
| Stroke | 14 | 58 | 28 | 16 | 62 | 22 |
| High Blood Pressure | 54 | 17 | 29 | 55 | 20 | 25 |
| Diabetes | 16 | 19 | 65 | 21 | 15 | 64 |

Basic trainees at this training installation are not permitted to smoke at any time or in any place during the training course. For this reason questions concerning smoking habits and tobacco use were phrased to capture information about habits prior to basic training. These results are summarized in Tables 11-14.

Despite the smoking ban during basic training, four male soldiers responded that they were still smoking cigarettes. Assuming this to be true, the probability of greatly restricted use was likely for these individuals. For this reason their results are included in the category of having quit smoking just prior to basic training.

A majority of both males (57%) and females (63%) responded that they had never smoked cigarettes prior to basic training. Five percent of the males and five percent of the females reported that they had stopped smoking cigarettes within the last six months and two percent of the males and six percent of the

females reported that they had stopped smoking over six months ago. Thirty-six percent of the males and twenty-six percent of the females responded to having quit smoking just prior to basic training. Similar results for male (33%) and female (27%) smokers had been reported for individuals under twenty-five years of age in the Jan-Jun 1988 Army Health Risk Appraisal Program (20).

The number of cigarettes that had been smoked daily and the number of years that these subjects had smoked cigarettes are presented in Tables 12 and 13 for those respondents who reported that they had stopped smoking just prior to basic training. One female did not respond to the question concerning the number of cigarettes smoked, thus the difference in the population size. The majority of the male and female smokers reported cigarette usage for less than four years. Male smokers reported a higher number of cigarettes smoked per day than female smokers. Given the young age of the population (males, mean age 19 years and females, mean age 20 years), the fact that five percent of the males and nine percent of the females reported cigarette usage for over ten years may seem unlikely; however, cigarette usage by children as young as eight years of age has been reported (51) and seems confirmed in the present study. The older recruits (>25 years of age) did not account for a majority of the number that reported smoking >10 years.

Subjects who had quit smoking cigarettes just prior to basic training were also asked about plans to continue smoking after basic training. Responses to this question by male trainees were: forty percent stated a desire to resume smoking; thirty-one percent said that they would not resume smoking; and, twenty-nine percent were uncertain. Female smokers responded to this question with less certainty. Fifty-six percent of the female smokers were uncertain

about future plans, while twenty-six percent said that they would not resume smoking, and only eighteen percent said that they would resume smoking cigarettes after basic training.

A small percentage of male subjects reported cigar, pipe, or smokeless tobacco usage on a daily basis (Table 14). No females reported any use of these products.

Thirty-five percent of the males and forty-five percent of the females stated that they never drank alcoholic beverages. The greater percentage of subjects who did respond positively to alcohol consumption reported drinking two days or less per week, which may be a reflection of social drinking on the weekend. Males reportedly drank a greater number of alcoholic beverages per week, but the majority of both males and females reported drinking fewer than 5-12 drinks per week.

Table 11. History of Cigarette Use by U.S. Army Basic Trainees Prior to Basic Training.

| | <u>% Males (N=128)</u> | <u>% Females (N=130)</u> |
|---------------------------|------------------------|--------------------------|
| Never Smoked | 57 | 63 |
| Quit Just Prior to Basic | 36 | 26 |
| Quit Within Last 6 Months | 5 | 5 |
| Quit Over 6 Months | 2 | 6 |

Table 12. Number of Cigarettes Smoked by Male and Female U.S. Army Basic Trainees Who Stopped Smoking Just Prior to Basic Training.

| <u>Amount</u> | <u>% Male (N=42)</u> | <u>% Female (N=33)</u> |
|--------------------|----------------------|------------------------|
| <1 pack per day | 14 | 33 |
| 1/2-1 pack per day | 31 | 28 |
| 1-2 packs per day | 48 | 33 |
| >2 packs per day | 7 | 6 |

Table 13. Length of Time That Cigarettes were Used by U.S. Army Basic Trainees Who Stopped Smoking Just Prior To Basic Training.

| <u>Time</u> | <u>% Males (N=42)</u> | <u>% Females (N=34)</u> |
|-------------|-----------------------|-------------------------|
| <1 year | 17 | 26 |
| 2-4 years | 55 | 56 |
| 5-10 years | 23 | 9 |
| >10 years | 5 | 9 |

Table 14. History of Other Tobacco Use by U.S. Army Basic Trainees Prior to Basic Training.

| | <u>% Males (N=128)</u> | | | <u>% Females (N=130)</u> | | |
|-------------------|------------------------|--------------|------------------|--------------------------|--------------|------------------|
| | <u>Never</u> | <u>Daily</u> | <u><Daily</u> | <u>Never</u> | <u>Daily</u> | <u><Daily</u> |
| Pipe or Cigar | 87 | 1 | 13 | 100 | 0 | 0 |
| Smokeless Tobacco | 84 | 5 | 11 | 100 | 0 | 0 |

Table 15. History of Alcohol Use by U.S. Army Basic Trainees Prior to Basic Training.

| <u>Days per week</u> | <u>% Males (N=128)</u> | <u>% Females (N=130)</u> |
|------------------------|------------------------|--------------------------|
| Never drink | 35 | 45 |
| <1 day/wk | 20 | 32 |
| 1 to 2 days/wk | 22 | 15 |
| 3 to 5 days/wk | 16 | 6 |
| 6 to 7 days/wk | 6 | 1 |
| <u>Drinks per week</u> | | |
| Don't drink | 35 | 45 |
| <4 | 29 | 40 |
| 5-12 | 13 | 8 |
| 13-20 | 10 | 2 |
| 21-30 | 7 | <1 |
| >31 | 3 | 0 |
| No Response | 3 | 4 |

Many of the subjects reported infrequent exercise habits prior to basic training (Table 16). Thirty-seven percent of the males and twenty-eight percent of the females reported participating in some type of aerobic exercise (minimum twenty minutes duration) more than three times per week. An even lower percentage of females (18%) reported performing some type of muscle strengthening exercise more than three times per week.

Table 16. Exercise History of U.S. Army Basic Trainees Prior to Basic Training.

| <u>SEX</u> | <u>FREQUENCY</u> | <u>Aerobic^a %</u> | <u>Muscle Strengthen^b %</u> |
|-------------------|------------------|----------------------------------|--|
| Male (N=128) | Rarely/Never | 39 | 38 |
| | 1-2 times/wk | 42 | 30 |
| | >3 times/wk | 37 | 32 |
| Female (N=130) | Rarely/Never | 43 | 48 |
| | 1-2 times/wk | 28 | 34 |
| | >3 times/wk | 28 | 18 |

^aAt least 20 min/day of activities such as running, fast walking, biking, swimming, rowing etc.

^bActivities such as pushups, situps, weight lifting, a Nautilus/Universal workout, resistance training, etc.

Of the 129 females who answered the question concerning the use of birth control pills, twenty-five percent responded positively. The information as to the types of birth control pills that were used was incomplete and unclear and therefore this information was excluded from this report.

Blood Lipid Profiles

An in depth blood lipid profile was determined for forty male and thirty-nine female basic trainees. These subjects had fasted for at least eleven

hours prior to having their blood drawn by venipuncture. The resultant sera were analyzed by both USARIEM and LSU for serum total cholesterol, triglycerides, and HDL cholesterol. Personnel at LSU also analyzed the sera for LDL and VLDL cholesterol. Because of the completeness of LSU's data, they were used in the discussion of blood lipid profiles for this basic trainee population. A comparison of the results obtained by both methods will be discussed in the following section. The serum total cholesterol of these 79 individuals were included in the preceding section which discussed the population screening for serum total cholesterol. The racial breakdown for this group was similar to that of the larger group: 23 white males (58%), 12 black males (30%), 5 hispanic males (12%), 24 white females (62%); 7 black females (18%), 7 hispanic females (18%), and 1 American Indian female (2%).

The results of the blood lipid determination are summarized in Tables 17-23. Mean serum total cholesterol levels for this group followed the same trends as the previously discussed larger group. White females tended to have a higher mean level of serum total cholesterol, LDL cholesterol and HDL cholesterol than did the white males in this sample of the population. However, the summary estimates that Castelli et al. (16) developed on the Framingham Heart study show that the mean total cholesterol to HDL cholesterol (TC/HDL) and the mean LDL cholesterol/HDL cholesterol (LDL/HDL) ratios were almost identical (Table 17) for both white males and females. A similar trend was found for both triglycerides and VLDL cholesterol (Table 18). Black females were found to have the highest mean level of HDL cholesterol (74 mg/dl) for all race/sex categories in this study. However, this may not be significant because of the relatively low number of black females in this

Table 17. Mean Serum Total Cholesterol (TC), LDL Cholesterol (LDL), and HDL Cholesterol Levels for Male and Female U.S. Army Basic Trainees of Various Races.

| SEX | RACE | N | TC ^a (mg/dl) | | LDL ^a (mg/dl) | | HDL ^a (mg/dl) | | MEAN TC/HDL | MEAN LDL/HDL |
|--------|------------|----|----------------------------|----|-----------------------------|----|-----------------------------|----|----------------|-----------------|
| | | | Mean | SD | Mean | SD | Mean | SD | | |
| Male | White | 23 | 140 | 30 | 88 | 29 | 47 | 10 | 3.07 | 1.97 |
| | Black | 12 | 165 | 27 | 97 | 24 | 59 | 14 | 2.94 | 1.78 |
| | Hispanic | 5 | 153 | 17 | 98 | 22 | 48 | 6 | 3.22 | 2.07 |
| | Total | 40 | 149 | 29 | 92 | 27 | 51 | 12 | 3.05 | 1.93 |
| Female | White | 24 | 169 | 23 | 104 | 20 | 57 | 11 | 3.07 | 1.91 |
| | Black | 7 | 165 | 35 | 85 | 28 | 74 | 19 | 2.33 | 1.22 |
| | Hispanic | 7 | 155 | 23 | 93 | 17 | 56 | 9 | 2.81 | 1.69 |
| | Am. Indian | 1 | 125 | - | 72 | - | 51 | 1 | 2.45 | 1.41 |
| | Total | 39 | 165 | 26 | 98 | 25 | 59 | 14 | 2.87 | 1.73 |

^aResults of serum analysis by LSU

Table 18. Mean Serum Triglycerides and VLDL Cholesterol Levels for Male and Female U.S. Army Basic Trainees of Various Races.

| SEX | RACE | N | Triglycerides ^a (mg/dl) | | VLDL ^a (mg/dl) | |
|--------|------------|----|---------------------------------------|----|------------------------------|----|
| | | | Mean | SD | Mean | SD |
| Male | White | 23 | 58 | 19 | 7 | 4 |
| | Black | 12 | 50 | 9 | 8 | 5 |
| | Hispanic | 5 | 60 | 10 | 7 | 4 |
| | Total | 40 | 56 | 16 | 7 | 5 |
| Female | White | 24 | 67 | 20 | 9 | 5 |
| | Black | 7 | 51 | 11 | 7 | 6 |
| | Hispanic | 7 | 61 | 26 | 6 | 6 |
| | Am. Indian | 1 | 43 | - | 2 | - |
| | Total | 39 | 63 | 21 | 8 | 5 |

^aResults of serum analysis by LSU

sample (N=7). For black females, the mean TC/HDL ratio (2.33) and mean LDL/HDL (1.22) ratio were also the lowest for any race/sex category. Black males had the highest mean HDL level (59 mg/dl) but the lowest mean TC/HDL (2.94) and mean LDL/HDL (1.78) ratios when compared to white or hispanic males (Table 17).

Overall, the females had slightly higher mean blood lipid levels than males and lower risk ratios (Table 17).

A comparison of blood lipid levels of males and females by age indicates that females had higher total, LDL, and HDL cholesterol levels than males of the same age group except for HDL cholesterol at the highest age group. The TC/HDL ratio was lowest for females 20-25 years of age and LDL/HDL the ratios were lowest for males 26 years of age and older (Table 19). The distribution of TC/HDL and LDL/HDL ratios is presented in Table 20 for the 79 males and females in this subsample. The mean triglyceride levels for this sample was within the low normal range (Table 21) and the VLDL cholesterol levels were not noticeably different from the the racial breakdown.

Table 19. Mean Serum Total Cholesterol (TC), LDL Cholesterol, and HDL Cholesterol Levels for Male and Female U.S. Army Basic Trainees of Various Age Groups.

| SEX | AGE GROUP | N | TC ^a | | LDL ^a | | HDL ^a | | MEAN | MEAN |
|--------|--------------|----|-----------------|----|------------------|----|------------------|----|--------|---------|
| | | | Mean | SD | Mean | SD | Mean | SD | TC/HDL | LDL/HDL |
| Male | <19 | 35 | 151 | 29 | 94 | 26 | 50 | 12 | 3.08 | 1.96 |
| | 20-25 | 4 | 133 | 32 | 77 | 37 | 53 | 19 | 2.81 | 1.74 |
| | >26 | 1 | 156 | - | 86 | - | 54 | - | 2.89 | 1.59 |
| | Total | 40 | 149 | 29 | 92 | 27 | 51 | 12 | 3.05 | 1.93 |
| Female | <19 | 29 | 161 | 27 | 96 | 22 | 58 | 13 | 2.87 | 1.73 |
| | 20-25 | 8 | 178 | 13 | 102 | 19 | 67 | 15 | 2.77 | 1.62 |
| | >26 | 2 | 173 | 45 | 114 | 45 | 52 | 5 | 3.41 | 2.26 |
| | Total | 39 | 165 | 26 | 98 | 22 | 59 | 14 | 2.87 | 1.73 |

^aResults of serum analysis by LSU

Table 20. Frequency of Male and Female U.S. Army Basic Trainees with TC/HDL and LDL/HDL Risk Ratios Within Specific Ranges.

| Range | TC/HDL RATIOS | | LDL/HDL RATIOS | |
|---------------|---------------|---------------|----------------|---------------|
| | MALE (N) | FEMALE (N) | MALE (N) | FEMALE (N) |
| <0.99 mg/dl | - | - | 3 | 2 |
| 1.0-1.5 mg/dl | 1 | - | 14 | 16 |
| 1.6-2.0 mg/dl | 1 | 4 | 9 | 13 |
| 2.1-2.5 mg/dl | 9 | 8 | 6 | 3 |
| 2.6-3.0 mg/dl | 11 | 13 | 5 | 5 |
| 3.1-3.5 mg/dl | 10 | 9 | 3 | - |
| 3.6-4.0 mg/dl | 4 | 2 | - | - |
| 4.1-4.5 mg/dl | 2 | 3 | - | - |
| 4.6-5.0 mg/dl | 2 | - | - | - |

Table 21. Mean Triglycerides and VLDL Levels for Male and Female U.S. Army Basic Trainees of Various Age Groups.

| SEX | AGE | Triglycerides ^a | | | | VLDL ^a | |
|--------|-------|----------------------------|----|------|----|-------------------|----|
| | | GROUP | N | Mean | SD | Mean | SD |
| Male | <19 | 35 | 57 | 16 | | 8 | 4 |
| | 20-25 | 4 | 45 | 15 | | 3 | 2 |
| | >26 | 1 | 63 | - | | 16 | - |
| | Total | 40 | 56 | 16 | | 7 | 5 |
| Female | <19 | 29 | 61 | 19 | | 7 | 5 |
| | 20-25 | 8 | 63 | 20 | | 9 | 7 |
| | >26 | 2 | 88 | 41 | | 8 | 5 |
| | Total | 39 | 63 | 21 | | 8 | 5 |

^aResults of serum analysis by LSU

Two male and three female basic trainees were found to be in the NCEP blood total cholesterol classification of borderline-high (200-239 mg/dl) (Table 22). An additional male and female were found to have LDL cholesterol levels above 130 mg/dl (borderline-high risk LDL cholesterol) although their blood total cholesterol levels were below 200 mg/dl (Table 22). Of the 5 basic trainees with borderline-high total cholesterol levels, one male with a

blood cholesterol level of 214 mg/dl was found to have a LDL cholesterol level of 161 Mg/dl which placed him in the NCEP's high risk LDL cholesterol classification. This individual also had a TC/HDL ratio of 4.6 and a LDL/HDL ratio of 3.4 which were the highest found within this study population.

Table 22. Blood Lipid Profiles^a of Male and Female U.S. Army Basic Trainees at Risk of CHD Based Upon Classifications of the NCEP.

| <u>SEX</u> | <u>TOTAL CHOLESTEROL (mg/dl)</u> | <u>LDL (mg/dl)</u> | <u>HDL (mg/dl)</u> | <u>TC/HDL RATIO</u> | <u>LDL/HDL RATIO</u> |
|------------|--|------------------------|------------------------|-------------------------|--------------------------|
| Male | 204 | 107 | 83 | 2.5 | 1.3 |
| Male | 214 | 161 | 47 | 4.6 | 3.4 |
| Male | 193 | 138 | 48 | 4.0 | 2.9 |
| Female | 204 | 145 | 48 | 4.3 | 3.0 |
| Female | 215 | 131 | 69 | 3.1 | 1.9 |
| Female | 204 | 123 | 69 | 3.0 | 1.8 |
| Female | 196 | 136 | 51 | 3.8 | 2.7 |

^aResults of serum analysis by LSU

Although the NCEP does not classify individuals into CHD risk categories according to HDL cholesterol levels, the program does use HDL cholesterol levels of below 35 mg/dl as an additional CHD risk factor (4). Four male basic trainees had HDL cholesterol levels of 35 mg/dl or below but their total cholesterol levels were well within the desirable category. The blood lipid profiles for these four individuals are presented in Table 23. No females were observed to have HDL cholesterol levels below 35 mg/dl.

Comparison of Blood Lipid Analysis Methods

Independent analyses were performed by USARIEM and LSU for serum total cholesterol, triglycerides, and HDL cholesterol using two different methodologies. A Kodak Ektachem DT 60 analyzer was used at USARIEM to analyze

Table 23. Blood Lipid Profiles^a of Male U.S. Army Basic Trainees with HDL Cholesterol Levels of 35 mg/dl or Below.

| CHOLESTEROL | | | TC/HDL | LDL/HDL |
|----------------|------------------|----------------|--------|---------|
| HDL (mg/dl) | TOTAL (mg/dl) | LDL (mg/dl) | RATIO | RATIO |
| 33 | 115 | 117 | 3.5 | 3.5 |
| 35 | 149 | 97 | 4.3 | 2.8 |
| 31 | 143 | 101 | 4.6 | 3.2 |
| 28 | 118 | 85 | 4.2 | 3.0 |

^aResults of serum analysis by LSU

serum for total cholesterol, triglycerides, and HDL cholesterol. LSU used an Abbott VP enzymatic analyzer to measure serum samples for total cholesterol and triglycerides. HDL cholesterol was determined directly by LSU by precipitating the serum's LDL plus VLDL component with heparin and Ca^{++} , and analyzing the supernate for HDL cholesterol by Abbott VP Super System, whereas the USARIEM Ektachem analysis measured HDL's directly following LDL and VLDL precipitation by dextran sulfate- Mg^{++} . Blood drawing methods, handling, shipping, storage procedures, and detailed methodologies have been presented in the Methods chapter.

Seventy-nine serum samples were analyzed independently for total cholesterol by the two laboratories. A paired t test was used to check for significant differences between the results of the two labs. The results of

this comparison are presented in Table 24. Although significant differences were found between the two methods for total cholesterol analysis, the means were very similar. The low inter-assay variability probably permitted the significant detection of this small difference. A mean difference of only 1.45 was calculated between the results obtained from the two methods. A correlation coefficient of 0.99 also was found for the two methods (Table 24). The maximum difference between the two methods for individual samples was 10 mg/dl. This maximum difference occurred in one of the 79 different comparisons. If the LSU method is chosen as a standard this means that the Kodak analyzer had a worst case accuracy of 5% on one sample. The mean accuracy of the Kodak analyzer was within 1% of the LSU method. The Kodak Ektachem DT 60 analyzer consistently provided lower results than the LSU method. Although the results between the two labs are significantly different, it can be concluded that the Kodak analyzer can provide simple and reliable measurement of total cholesterol.

A comparison of the two methods for triglyceride analysis was conducted on seventy-five serum samples. The USARIEM lab was unable to analyze four serum samples because of insufficient sample size. A comparison of the two methods of triglyceride analysis by paired t test also found significant differences between the two different methods. However, the means were very similar with a mean difference of 3.58 and a correlation coefficient of 0.93. The Kodak Ektachem DT 60 analyzer again provided consistently lower results.

Only seventy-two serum samples were analyzed for the comparison of HDL cholesterol. Three serum samples which had been analyzed on the Kodak Ektachem DT 60 analyzer provided values that were outside the analytical range

of the instrument and four HDL cholesterol values were lost due to a malfunction in the instrument's recording device. Sufficient samples were not available for re-analysis.

A comparison between the two methods of HDL cholesterol analysis by a paired t test also revealed significant differences between the LSU and USARIEM methods. A larger mean difference (5.84) was calculated for this comparison than had appeared for total cholesterol and triglycerides. A lower correlation coefficient of 0.67 was obtained between the two methods for HDL cholesterol determination. In this instance the Kodak DT 60 analyzer consistently provided higher HDL cholesterol values than the method of LSU. The differences in HDL cholesterol values are not surprising considering the differences in methodologies for HDL determination utilized by the two laboratories. Both methods rely upon the quantitative precipitation of LDL and VLDL by dextran sulfate or heparin precipitation. This precipitation is probably the most likely source of error or disagreement between the two assays.

Table 24. Comparison of the Analysis for Serum Total Cholesterol, Triglycerides, and HDL Cholesterol by Two Different Methods.

| <u>ANALYSIS</u> | <u>METHOD</u> | <u>N</u> | <u>MEAN</u> | <u>SD</u> | <u>(DIFFERENCE)</u> <u>MEAN</u> | <u>t</u> |
|-------------------|---------------|----------|-------------|-----------|------------------------------------|----------|
| Total Cholesterol | Kodak DT 60 | 79 | 155.24 | 28.08 | -1.45* | .99 |
| | LSU | 79 | 156.69 | 28.55 | | |
| Triglycerides | Kodak DT 60 | 75 | 54.58 | 20.20 | -3.58* | .93 |
| | LSU | 75 | 58.17 | 17.58 | | |
| HDL Cholesterol | Kodak DT 60 | 72 | 59.62 | 18.28 | 5.84* | .67 |
| | LSU | 72 | 53.77 | 12.32 | | |

*Significant at the 0.05 level

Overall, there was relatively good agreement between these two methods with the LSU method being somewhat more conservative than the Kodak Ektachem method. The Kodak Ektachem appears to be a good analyzer for rapid screening for cholesterol-cardiovascular risk. Individuals testing in the over 200 mg/dl total cholesterol or under 35 mg/dl for HDL cholesterol should be tested by a more rigorous method such as the LSU method prior to receiving recommendations for dietary modification or medical treatment.

CONCLUSIONS

Blood lipid levels determined for this sample of U.S. Army Basic Trainees were representative of blood lipid levels expected for males and females reaching the end of adolescence and entering early adulthood. Population means for serum total cholesterol levels followed similar age, race, and gender trends as identified in the large population studies.

The majority of these young individuals had blood cholesterol levels well within the desirable blood cholesterol classification (mean \pm SD for males 140 ± 25 , females 162 ± 28) identified by the Adult Treatment Panel of the National Cholesterol Education Program. However, the majority of these young individuals may not yet have begun to increase their total cholesterol levels as may be expected later in life due to an "adolescent drop" common among 16-20 year olds. Further, low levels observed during this period of life should not reduce awareness that coronary atherosclerotic lesions are developing in young military personnel as seen in the autopsy experience in the military. Alertness to CHD risk factors should remain a high priority.

Although a relatively small percentage of subjects (9% females, 3% males) were identified with total cholesterol levels exceeding 200 mg/dl, these incidents indicate that intervention has to begin early. Experience with military populations has demonstrated that individuals only a few years older than this study sample are at greater risk of CHD due to elevated cholesterol levels. Reasons for this trend may include: diet, genetics, aging, and/or any of the other causes leading to elevated blood cholesterol levels. Unfortunately the entire disease process is very complex and no one specific reason may be at fault for all individuals.

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APPENDIX A

DoD Food and Nutrition RDTE&E Requirements FY 91

DoD Food and Nutrition RDTE&E Requirements FY 81

Nutrition Research

SUBJECT: Garrison Dining Facility Study of Basic Trainee Population

1. Statement of Need:

a. Statement of Requirement: A need exists for an assessment of nutrient intakes of basic trainees during BCT. Garrison dining facility studies have been conducted at FT Riley, KS; FT Lewis, WA, and FT Devens MA. Because of the unique requirements and time restrictions in the BCT environment, it is anticipated that the impact of nutrition initiatives and subsequent soldier caloric and nutrient intake may vary from the populations studied previously. In order to make sound recommendations for change in training practices that impact on nutrition and possibly meal schedules, additional information is needed.

b. Priority: Urgent

2. Time Frame: FY 89

3. Threat/Operational Deficiency: DA Food Service staff have sought to change practices in garrison dining facilities serving basic trainees. However because no detriment to soldier health and performance has been shown, commanders have permitted no significant changes. Trainees are allowed minimum time to consume meals with little opportunity to select from the many options available.

4. Operational Concept: The product of this effort will result in recommended changes to policies governing garrison dining facilities for basic trainees.

5. Essential Characteristics: Issues to be investigated include: caloric and nutrient intakes of basic trainees compared to soldiers in a more typical military environment; time allowed for meal consumption; and a blood cholesterol and triglyceride analysis to determine the percentage of this unique population that exceed the desirable level of 200 milligrams of serum cholesterol per deciliter of blood.

6. Technical Assessment: Effort to be conducted by USARIEM with support from USANRDEC as required.

7. Cost Estimate: To be determined by laboratory.

8. Originating Agency: HQDA, Office of the Surgeon General (DASG-DBD)

APPENDIX B
USARIEM Human Use Review Committee Approval

DISPOSITION FORM

For use of this form, see AR 340-10; the proponent agency is TAGO.

| | | | | |
|--|-----------|--|-------|--|
| REFERENCE OR OFFICE SYMBOL | | SUBJECT | | |
| SGRD-UEZ (70-1n) | | Report of the USARIEM Human Use Review Committee | | |
| TO | FROM | DATE | GMT 1 | |
| C, Mil Nutr Div | Commander | 7 June 1988 /atw/4811 | | |
| <p>1. The USARIEM Human Use Review Committee has reviewed and recommended approval of your protocol entitled "Nutritional Assessment and Cardiac Risk Appraisal of U.S. Army Basic Trainees," HURC #338. The Decisions and Recommendations of the Committee are attached.</p> <p>2. The Committee recommended approval of this study on condition that the points mentioned be appropriately modified or corrected. Following receipt of your response, I will forward your protocol to the Human Use Office at our Headquarters for their final approval.</p> | | | | |
| <p>Encl</p> <p><i>David Schnakenberg</i> DAVID D. SCHNAKENBERG Colonel, MS Commanding</p> | | | | |

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PREVIOUS EDITIONS WILL BE USED

48

2025 RELEASE UNDER E.O. 14176

APPENDIX C

OTSG Human Use Review Committee Approval



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

FILE

7/14/88
ext

SGRD-HR

14 July 1988

MEMORANDUM FOR: Commander, U.S. Army Research Institute of Environmental Medicine, ATTN: SGRD-UE-2, Natick, MA 01760-5007

SUBJECT: Protocol Entitled "Nutritional Assessment and Cardiac Risk Appraisal of U.S. Army Basic Trainees," HURC #338, Submitted by LTC Eldon W. Askew, MS, USARIEM (Log No. A-4689)

1. Revisions submitted in response to recommendations of the Acting Chairman, Human Subjects Research Review Board have been reviewed and found to satisfactory.
2. This study is approved for implementation.
3. Reference memorandum, SGRD-UE-2, 1 Jul 88, SAB.
4. Should you have any questions concerning this matter, please contact the Human Use Review and Regulatory Affairs Office at AUTOVON 343-2165 or (301) 663-2165.

GREGORY P. BEREZUK
LTC, MS
Chief, Human Use Review and
Regulatory Affairs Office

APPENDIX D
Approval for Study Location

PCV MSG 0 TIME RADAY
27344 1239 034/08

PRICE

*Nutrition
C. J. Cdt*

CCR--HTL--~~HTL~~--NAVY--DC--TD--XO--RD--BCH--IG--CEO--IRACO--OEO--PAO--
PROTO--BNDGUS--RHED--RSCD--DPR--PSCAD--RHD--DEPH--DODFD--IND--LEBHD--FLAO--
FED--FIO--NC--NRCG--IPL--RCLNG--GCC--SAFETY--SATD--TRAN8--LE&SO--TCC--OTHER

PTTUZYUW RUEARH00096 0382315-UUUU--RUEADHTA.

ZNA UUUUU

P 022130Z FEB 88

FM DA WASHDC //DHALO-TST-F//
TO RUEADHTA/CORUSARIEN Natick MA //SGRD-UE-N//
INFO RUECLIAA/CDR TRADOC FT ROME VA//WTPL-TS//
RUEOAGG/CORTSA FT LEE VA //DHALO-TAF-D//
RUEADWD/NG DA WASHDC //DASC-RDZ//

BT

UNCLAS

SUBJECT: USARIEM EVALUATION OF NUTRITION INITIATIVES IN GARRISON
DINING FACILITIES

A. HODA (DHALO-TST) MSG, 111507Z JAN 88, SAB.

1. REFERENCE A REQUESTED TRADOC AND FORT JACKSON'S ASSISTANCE IN
IDENTIFYING SPECIFIC BASIC TRAINING DINING FACILITIES WHERE USARIEM
COULD CONDUCT AN EVALUATION OF GARRISON DINING NUTRITION
INITIATIVES.

2. PER PHENOMENON BETWEEN CPT JACKSON, TRADOC FOOD SERVICE AND OFFICE
AND MSG ADOLPHI, HODA ON SAB, THE FOLLOWING FACILITIES AT FORT
JACKSON HAVE BEEN IDENTIFIED FOR USARIEM'S STUDY:

PRIMARY FACILITY: BUILDING 11000

ALTERNATIVE FACILITY: BUILDING 12000.

PAGE 02 RUEADWD00096 UNCLAS

3. INSTALLATION FOOD SERVICE POINTS OF CONTACT INCLUDE CPT FOPPE
AND SGM MANOH, AV 734-5083/4015.

4. HODA (DHALO-TST) POC IS MSG. ADOLPHI, AV 225-1201.

BT

00096

NNNN

APPENDIX E
Volunteer Agreement Affidavit

VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 40-38; the proponent agency is the Office of the Surgeon General

THIS FORM IS AFFECTED BY THE PRIVACY ACT OF 1974**1. AUTHORITY:** 10 USC 3012, 44 USC 2101 and 10 USC 1071-1087.**2. PRINCIPAL PURPOSE:** To document voluntary participation in the Clinical Investigation and Research Program. SSN and home address will be used for identification and locating purposes.**3. ROUTINE USES:** The SSN and home address will be used for identification and locating purposes. Information derived from the study will be used to document the study; implementation of medical programs; teaching; adjudication of claims; and for the mandatory reporting of medical condition as required by law. Information may be furnished to Federal, State and local agencies.**4. MANDATORY OR VOLUNTARY DISCLOSURE:** The furnishing of SSN and home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this investigational study.**PART A - VOLUNTEER AFFIDAVIT****VOLUNTEER SUBJECTS IN APPROVED DEPARTMENT OF THE ARMY RESEARCH STUDIES**

Volunteers under the provisions of AR 70-25 are authorized all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

I, _____ SSN _____ having
(last, first, middle)
full capacity to consent and having attained my _____ birthday, do hereby volunteer to participate in
_____ NUTRITIONAL ASSESSMENT AND CARDIAC RISK APPRAISAL OF U.S. ARMY BASIC TRAINEES
(research study)under direction of _____ Mr. Robert W. Rose _____ conducted at _____ Fort Jackson, S.C.
(name of institution)The implications of my voluntary participation; the nature, duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by
Mr. Robert W. Rose _____

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights on study-related injury I may contact

Office of Chief Counsel, Natick Research, Development, and Engineering Center
at _____ Natick, MA 01760 (617) 651-4322
(name and address of keeper/ or phone number (617) 651-4322)I understand that I may at any time during the course of this study revoke my consent and withdraw from the study without further penalty or loss of benefits however, I may be required (military volunteer) or requested (civilian volunteer) to undergo certain examination if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.**PART B - TO BE COMPLETED BY INVESTIGATOR****INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT:** (Provide a detailed explanation in accordance with Appendix E, AR 40-38 or AR 70-25.)

-See back of page

(CONTINUE ON REVERSE)

PART B - TO BE COMPLETED BY INVESTIGATOR (ARMED)

This study is designed to determine your food nutrient consumption when eating in a garrison dining facility and to determine your potential risk of developing cardiac problems in the future. You will be asked to complete questionnaires, provide verbal information, and provide blood samples from either the finger tip or a vein in your arm. Blood samples will be taken only once and there is a small chance of inflammation at the site of the needle puncture. Sanitary techniques will be used and the procedures and safety standards that we use in testing meet with the safety standards set up at USARIEM for Human Research Studies. Doctors at the Fort Jackson Health Clinic will be standing by in the very unlikely event that treatment is required.

Your risk of developing cardiac problems will be determined by comparing your blood cholesterol levels and your background medical information with guidelines established by the National Institute of Health. If your results indicate that some type of treatment is required you will be notified. The results obtained from this study are only preliminary and do not constitute a final medical diagnosis.

Food consumption will be determined by two different methods. We will be monitoring actual observed food consumption for a small group of volunteers for 3 meals/day for 7 days plus 2 meals. The small group will be asked to show their trays of food to data collectors before eating and again after eating. We will work quickly so that your food will not get cold. A larger group will be asked to complete a food diary after each meal for 3 meals/day for 3 days. The results from both methods will be compared with military guidelines for optimal nutrient intakes to determine how well the food you have eaten meets nutritional standards.

You will be asked to answer questions about your background, medical history and past dietary patterns and attitudes. This information will help us further analyze your food consumption. You may also be asked to be weighed at the start of the study and again at the end. All data obtained about you as an individual will be considered privileged and held in confidence; you will not be identified in any presentation of the results. Complete confidentiality cannot be promised, particularly to subjects who are military personnel, because information bearing on your health may be required to be reported to appropriate medical or Command authorities, and applicable regulation "notes the possibility that the Food and Drug Administration and U.S. Army Medical Research and Development Command officials may inspect the records."

You will receive no direct benefits from your participation in this study other than a blood cholesterol value and the knowledge and experience you may gain from the study procedures. If you have any questions concerning the study or the results obtained, please contact the primary individual responsible for the study: Mr. Robert Rose. He will be present at Fort Jackson during the study. His permanent duty station is Military Nutrition Division, U.S. Army Research Institute of Environmental Medicine, Natick, MA 01760-5007. Autovon telephone number is 256-4803.

We ask you to be conscientious in providing complete information, as your cooperation is crucial to the success of the study. If a blood sample is needed, approximately 1 tablespoon of blood will be taken.

You will be given a copy of this form for your records.

| | | |
|--------------------------------|--|--|
| SIGNATURE OF VOLUNTEER | DATE SIGNED | SIGNATURE OF LEGAL GUARDIAN // <small>(if minor)</small> |
| PERMANENT ADDRESS OF VOLUNTEER | TYPED OR PRINTED NAME AND SIGNATURE OF WITNESS | DATE SIGNED |

APPENDIX F
Volunteer Registry Data Sheets

VOLUNTEER REGISTRY DATA SHEET

THIS FORM IS AFFECTED BY THE PRIVACY ACT OF 1974

1. **AUTHORITY:** 5 USC 301; 10 USC 1671-1690; 44 USC 3101; 20 CFR 3997
2. **Principal and Routine Purposes:** The document participation in research conducted or sponsored by the U.S. Army Medical Research and Development Command. Personal information will be used for identification and location of participants.
3. **Mandatory or Voluntary Disclosure:** The furnishing of the SSN is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your participation in the research study.

PART A-INVESTIGATOR INFORMATION
(To Be Completed By Investigator)

PLEASE PRINT, USING INK OR BALLPOINT PEN

| | | |
|---|--|--|
| 1. Study NR: <u>88-5</u> | 2. Protocol Title: <u>Nutritional Assessment and Cardiac Risk Appraisal of U.S. Army Basic Trainees.</u> | |
| 3. Contractor (Laboratory/Institute Conducting Study): | | |
| 4. Study Period: From: <u>31/07/88</u> To: <u>11/08/88</u> <u>(DAJMOYR)</u> <u>(DAJMOYR)</u> | | |
| 5. Principal/Other Investigator(s) Name(s) | | |
| (1) <u>Rose</u> <u>(Last)</u> | <u>Robert</u> <u>(First)</u> | <u>W.</u> <u>(MI)</u> |
| (2) <u>Szeto</u> | <u>Eileen</u> | <u>G.</u> |
| (3) <u>Baker</u> | <u>Carol</u> | <u>J.</u> |
| | | 6. Location/Laboratory |
| | | <u>USARIEM</u> / <u>Military Nutrition Div</u> |
| | | <u>USARIEM</u> / <u>Military Nutrition Div</u> |
| | | <u>USARIEM</u> / <u>Military Nutrition Div</u> |

PART B-VOLUNTEER INFORMATION
(To Be Completed By Volunteer)

PLEASE PRINT, USING INK OR BALLPOINT PEN

7. SSN: ___/___/___ 8. Name: ___
(Last) (First) (MI)

9. Sex: M_F 10. Date of Birth: ___/___/___ 11. *MOS/Job Series: ___ 12. *Rank/Grade: ___

13. Permanent Home Address (Home of Record) or Study Location Address:

(Street) *(P.O. Box/Apartment No.)*
(City) *(Country)* *(State)* *(Zip Code)*
(Perm Home Phone No.)

14. *Local Address (If Different From Permanent Address):

(Street) _____ (P.O. Box/Apartment No.) _____
(City) _____ (Country) _____ (State) _____ (Zip Code) _____
(Local Phone No.) _____

15. • Military Unit: _____ Zip Code: _____

Organization: _____ Post: _____ Duty Phone No. () -

USAMRMC Form 60-R Revised 1 Apr 88 (Supersedes previous editions)

PART C-ADDITIONAL INFORMATION
(To Be Completed By Investigator)

PLEASE PRINT, USING INK OR BALLPOINT PEN

16. Location of Study:

17. Is Study Completed: **Y** **N**

Did volunteer finish participation: **Y** **N** If YES, Date finished: **1/1/**
(DA/MO/YR)

If NO, Date withdrawn: **1/1/**
(DA/MO/YR) Reason withdrawn:

18. Did Any Serious or Unexpected Adverse Incident or Reaction Occur: **Y** **N** If YES, Explain:

19.*Volunteer Followup: _____

Purpose: _____

Date: **1/1/** Was contact made: **Y** **N** If No action taken, explain:
(DA/MO/YR)

20.*Hard Copy Records Retired: Place: _____ File NR: _____

21.*Product Information:

Product: _____

Manufacturer: _____

Lot NR: _____ Expiration Date: _____

NDA NR: _____ IND/IDE NR: _____

*Indicates that item may be left blank if information is unavailable or does not apply.

Entries must be made for all other items.

APPENDIX G
Demographics and Medical History Questionnaire

I. Background information:

Subject No. (to be supplied by tester) _____

1. Indicate AGE at last birthday. _____

2. Indicate your SEX. _____

3. Check the space next to your RACE/ETHNIC BACKGROUND.

Caucasian
 Black
 Oriental

Hispanic
 Other (Specify) _____

4. What is your current HEIGHT? _____ WEIGHT? _____

5. How much did you weigh when you entered the Army? _____

6. Are you trying to lose weight? (1) Yes (2) No
How much? _____

7. Are you trying to gain weight? (1) Yes (2) No
How much? _____

8. Indicate your HIGHEST LEVEL OF EDUCATION

(1) Some grade school
 (2) Finished grade school
 (3) Some High School
 (4) High School Graduate (includes GED)
 (5) Skilled Job Training
 (6) Some College
 (7) College Graduate

9. How long have you been in MILITARY SERVICE?
____ years ____ months ____ days

10. What is your Army RANK? _____

11. What JOB (mos) do you plan to do in the Army? _____

12. What is your MARITAL STATUS?

(1) Single, never married and not living as married
 (2) Married or living as married
 (3) Separated and not living as married
 (4) Divorced and not living as married
 (5) Widow/Widower and not living as married

13. In what REGION OF THE COUNTRY did you LIVE THE LONGEST before you joined the Service? (choose one)

- (1) New England (ME, NH, VT, MA, RI, CT)
- (2) Middle Atlantic (NY, NJ, PA)
- (3) East North Central (OH, IN, IL, MI, WI)
- (4) West North Central (MN, IA, MO, SD, ND, KS)
- (5) South Atlantic (DE, MD, DC, VA, WV, NC, SC, GA, FL)
- (6) East South Central (KY, TN, AL, MS)
- (7) West South Central (AK, LA, OK, TX)
- (8) Mountain (MT, ID, WY, CO, NM, AZ, UT, NV)
- (9) Pacific (WA, OR, CA, AK, HI)
- (10) Other (Territories, Possessions, or Countries)

II. Medical History

14. Have you been informed in the last 5 years that your blood pressure was high or borderline high?

(1) No (2) Yes, high
 (3) Yes, borderline

15. Are you being treated for high blood pressure?

(1) Yes (2) No

16. What is your blood cholesterol level?

(1) Never had it measured
 (2) I had it measured but don't remember
 (3) Under 200mg%
 (4) Between 200 and 250mg%
 (5) Over 250mg%

17. Have any of your close blood relatives (parent, grandparent, brother, or sister) had a HEART ATTACK before age 60?

(1) Yes (2) No (3) Don't know

18. Have any of your close blood relatives (parent, grandparent, brother, or sister) had a STROKE before age 60?

(1) Yes (2) No (3) Don't know

19. Have any of your close blood relatives (parent, grandparent, brother, or sister) had HIGH BLOOD PRESSURE before age 60?

(1) Yes (2) No (3) Don't know

20. Have any of your close blood relatives (parent, grandparent, brother, or sister) had DIABETES?

(1) Yes (2) No (3) Don't know

21. Have any of your close blood relatives (parent, grandparent, brother, or sister) had high blood cholesterol levels?

(1) Yes (2) No (3) Don't know

22. Do you smoke cigarettes now?

(1) Yes* (2) No, "I quit in the last 6 months"**
 (3) No, "I quit over 6 months ago"**
 (4) No, "I quit at the start of basic"**
 (5) No, "I never smoked"

* Answer #23

** Answer #24

23. How much do you smoke now?

(1) "I don't smoke" (2) Less than a half-pack a day
 (3) One-half to one pack a day
 (4) One to two packs a day
 (5) Two or more packs a day

24. How much did you smoke before you quit?

(1) "I don't smoke" (2) Less than a half-pack a day
 (3) One-half pack a day
 (4) One to two packs a day
 (5) Two or more packs a day

25. How long have you or did you smoke?

(1) "I don't smoke" (2) less than 1 year
 (3) 2 - 4 years
 (4) 5 - 10 years
 (5) More than 10 years

26. Do you want to stop smoking?

(1) "I don't smoke" (2) "I would like to quit NOW"
 (3) "I would like to quit SOMEDAY"
 (4) "I don't want to stop smoking"

27. How often do you smoke a pipe or cigar?

(1) Never (2) Less than daily
 (3) Daily

28. How often do you use smokeless tobacco such as chewing tobacco or snuff?

(1) Never (2) Less than daily
 (3) Daily

29. Respond to this statement only if you quit smoking at the start of basic training. "After basic training I intend to continue to SMOKE cigarettes."

(1) Yes (2) No (3) Don't know

30. In a typical week, how many days do you have at least one drink of alcohol (beer, wine, or liquor)?

(1) "I don't drink" (2) 6 or 7 days per week
 (3) 3 to 5 days per week (4) 1 to 2 days per week
 (5) Not even 1 day every week

31. In a typical week, how many drinks do you usually drink?

(1) "I don't drink" (2) 4 or less
 (3) 5 to 12 (4) 13 to 20
 (5) 21 to 30 (6) More than 30

32. Before coming into the Army, how often did you do at least 20 minutes of non-stop aerobic activity (vigorous exercise that greatly increases your breathing and heart rate such as running, fast walking, biking, swimming, rowing, etc.)?

(1) 3 or more times per week
 (2) 1 or 2 times per week
 (3) rarely or never

33. Before coming into the Army, how often did you do exercises that improve muscle strength, such as pushups, sit-ups, weight lifting, a Nautilus/Universal workout, resistance training, etc.?

(1) 3 or more times a week
 (2) 1 or 2 times a week
 (3) rarely or never

34. Females only: Do you take birth control pills?

(1) No (2) Yes
Specify type _____

APPENDIX H
Cholesterol Information Letter

US Army Research Institute
of Environmental Medicine
Natick
Massachusetts 01760-5007

Dear Private *****:

Thank you for helping us and taking part in our surveys. The information which you have supplied and the remainder that we have collected, will now take some time to analyze and interpret. The results though, once complete, will enable food service personnel to provide you with a better, more nutritious diet in the future.

The results themselves will of course be treated in the strictest confidence although you may be interested in those which we now have on your blood cholesterol levels.

Your Blood Cholesterol Level was *** mg/dl and this is considered to be Borderline.

Borderline Level: 200-239 mg/dl

Your blood cholesterol level is 'Borderline' and you should inform the Medical Officer so that you can be evaluated for heart disease risk factors. While high blood cholesterol is an important risk factor for heart disease, other factors may also increase your risk; for example, smoking and high blood pressure. If either these are the case, your risk of heart disease is increased regardless of the level of cholesterol. An information sheet on Cholesterol and Heart Disease is on the back of this letter.

It must be emphasized however that these results are only preliminary and that if you are in any doubt or have any worries concerning cholesterol you should consult a Medical Officer.

US Army Research Institute
of Environmental Medicine
Natick
Massachusetts 01760-5007

Dear Private *****:

Thank you for helping us and taking part in our surveys. The information which you have supplied and the remainder that we have collected, will now take some time to analyze and interpret. The results though, once complete, will enable food service personnel to provide you with a better, more nutritious diet in the future.

The results themselves will of course be treated in the strictest confidence although you may be interested in those which we now have on your blood cholesterol levels.

Your Blood Cholesterol Level was *** mg/dl and this is considered to be Desirable.

Desirable Level: Below 200 mg/dl

Your blood cholesterol level is considered 'Desirable' if it is below 200 mg/dl, although there are risk factors you may need to control to be sure your risk of heart disease is reduced. An information sheet on Cholesterol and Heart Disease is on the back of this letter.

It must be emphasized however that these results are only preliminary and that if you are in any doubt or have any worries concerning cholesterol you should consult a Medical Officer.



Are You At Risk for Heart Disease?

Even though the number of deaths due to heart disease is declining, coronary heart disease is still the number one cause of death in the U.S.

After years of research, scientists still cannot say with certainty what causes heart disease or who will have a heart attack. However, scientists have identified several risk factors associated with heart disease for the general population.

What are the risk factors?

Heredity, sex, age, high blood pressure, smoking, high blood cholesterol, lack of exercise, stress, diabetes, and overweight are risk factors for heart disease. We do not know if these risk factors cause the disease. However, we do know that people with heart disease often have many of these risk factors.



Cholesterol Facts

What is cholesterol?

- Cholesterol is a waxy substance that comes from two sources—your own body and food.
- Cholesterol is an essential part of the human body. It must be present for the body to function normally.

Your body needs cholesterol

Despite what you may have heard, cholesterol is not all bad. In fact, your body needs cholesterol to function.

Cholesterol is so vital that your body produces its own supply. Your body makes about 500-1000 mg (milligrams) of cholesterol a day. That's about 2/3 of your body's total cholesterol.

The other 1/3 of your body's cholesterol comes from the food you eat. Although everyone is different, on the average, foods contribute the following amounts of cholesterol to the daily diet:

- Milk Group 43-65 mg
- Meat Group 172-262 mg
- Fruit-Vegetable Group 2-3 mg*
- Grain Group 8-12 mg*
- "Others" Category—fats, sweets, alcohol 21-32 mg
- Combination Foods—foods made with ingredients from more than one food group 18-27 mg

*Plant foods do not normally contain cholesterol. Other ingredients from animal sources used to prepare foods in the Grain and Fruit-Vegetable Groups add small amounts of cholesterol to these products.

People differ in the amount of cholesterol their bodies need. However, a good rule of thumb for a healthful diet is:

Eat a wide variety of foods from the Basic Four Food Groups in moderation.

So, remember these three guidelines for keeping your cholesterol intake and your total nutritional picture in balance:

- The Basic Four Food Groups
- Variety
- Moderation

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